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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/810,988	03/16/2001	Gerhard Scheuch	RVOS-E1341US	7304

20808 7590 09/30/2009

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EXAMINER	
OSTRUP, CLINTON T	

ART UNIT	PAPER NUMBER
3771	

NOTIFICATION DATE	DELIVERY MODE
09/30/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	09/810,988	SCHEUCH ET AL.	
	Examiner	Art Unit	
	CLINTON OSTRUP	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25,28,38 and 42-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25,28,38 and 42-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 March 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is in response to the amendment filed June 19, 2009. As directed by the amendment, claims 25, 38, 43, and 44 have been amended and claims 48-55 have been added. Claims 1-24, 26-27, 29-37, and 39-41 are cancelled. Thus, claims 25, 28, 38, 42-55 are pending in this application.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: Reference character 18 is not mentioned in the specification. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 25, 28, 38, 42-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claims 25, 43, and 44 are confusing because it is unclear if "a predetermined aerosol deposition in a lung of a patient" is regarding a particular medicament in aerosol form, or if the aerosol deposition is a predetermined amount, concentration, or dose of an aerosolized medicament.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 25, 28, 38, 42-44, and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brand (6,606,989), which is the English equivalent of (WO98/52633) in view of Brooker (6,269,810) taken together with Goodman et al (5,542,410).

Brand discloses a method for administering a controlled inhalation of an aerosol for a patient during breathing maneuvers; however, the controlling of the air flow through the device during the controlled inhalation is not disclosed. The hardware of the system seems to be similar to that of the applicant with the exception of the modifications involving the controlling and adjustability with respect to the individual patient.

However, Brooker discloses inputting into an inhalation device a plurality of parameters which include both aerosol and patient specific parameters, individually adjusting the inhalation device to the patient by adapting a dosage of an aerosol on the basis for the previous parameters by evaluating the parameters and adjusting a flow or tidal volume of the device based on the aerosol parameters such that an optimal dose of the aerosol is delivered to a specific location in the lungs during controlled inhalation and controlling the air flow through the device using the device during controlled inhalation. Brooker also discloses a method for administering a controlled inhalation of an aerosol for a patient during breathing maneuvers including inputting into an inhalation device a plurality of parameters which include both aerosol and patient specific parameters, individually adjusting the inhalation device to the patient by adapting a dosage of an aerosol on the basis for the previous parameters by evaluating the parameters and adjusting a flow or tidal volume of the device based on the aerosol parameters such that an optimal dose of the aerosol is delivered to a specific location in the lungs during controlled inhalation and controlling the air flow through the device using the device during controlled inhalation. See col. 6 lines 12-51; col. 7 lines 19-48, col. 12 lines 24-42 and col. 13 line 40-col. 14 line 20. The tidal volume and capacity are previously determined by pulmonary tests. The data used to program the device includes aerosol parameters, device parameters and patient specific parameters. See: col. 7 lines 32-48.

Goodman teaches an apparatus that releases one or more pulses at the appropriate points in the patient's inspiratory flow to optimize the deposition of the

administered aerosolized medication within the desired loci within the lung. Goodman also teaches that the apparatus also may adjust the controlled amount of medication delivered and/or the particle size in each dosage of medication delivered in response to detected changes in the patient's pulmonary function. See: col. 16, lines 36-43.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the method taught by Brand to include the hardware and software changes taught by Brooker which are necessary to allow for the inputting of aerosol and patient specific parameters into the inhalation device to cause it to alter the air flow through the device depending on the patients requirements, and administered one or more pulses of aerosolized medicament at appropriate points in the patient's inspiratory flow, as taught by Goodman in order to obtain an aerosol medicament delivery device that allows for specific tailoring of medicament to the lungs of a patient which would deliver accurate dosages of aerosolized medication based on the particular patient's needs, which would greatly increase the accuracy and the correct dosing delivered to a particular patient.

8. Claims 45-47 and 50-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brand (6,606,989), which is the English equivalent of (WO98/52633) in view of Brooker (6,269,810) and Goodman et al (5,404,871) and further in view of Willemot (5,560,353).

The combined references teach discloses the method as claimed with the exception of the use of a smart card or memory card to program the inhalation device.

Willemot discloses that it was known to use such memory cards as input devices for inhalation devices. See: col. 1, lines 42-48; col. 2, lines 35-39; col. 2, line 59 - col. 3, line 30.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have had a physician program patient and drug data, for example, onto a memory card for placement into a reading device connected to the control means of the inhalation device, as this allows for safe transmission and a proper treatment regimen for each specific patient. Providing a device with the capability to read and alter the controls of the inhalation device, using the data from the card, would have been desired in order to have increased the effectiveness and the adaptability of using the device for the treatment on different patients. One of skill in the art would have had a reasonable expectation of success in achieving predictable results while simultaneously making the system more user friendly and adaptable to different patient populations requiring different drug treatment regimens.

9. Claim 48 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brand (6,606,989), which is the English equivalent of (WO98/52633) in view of Brooker (6,269,810) and Goodman et al (5,404,871) and further in view of Servidio, et al (5,598,838).

The combined references teach the invention as claimed with the exception of the modem. Servidio discloses that it was known to upload or download data to a respiratory device via a modem. See: col. 6, lines 31-39 and figure 1.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided the system of Brooker with a modem, as taught by Servidio, in order to be able to provide the device with data remotely.

Response to Arguments

10. Applicant's arguments with respect to claims 25, 28, 38, 42-55 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CLINTON OSTRUP whose telephone number is (571)272-5559. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Clinton Ostrup/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771